UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

TAKEDA PHARMACEUTICAL COMPANY LTD., et al., Plaintiffs,	12 Civ. 24 (DLC)
-v-	OPINION & ORDER
MYLAN, INC., et al., Defendants.	

Appearances

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DENISE COTE, District Judge:

Takeda Pharmaceutical Company Limited, Takeda Pharmaceuticals North America, Inc., Takeda Global Research and Development Center, Inc., Watson Pharmaceuticals, Inc., and Andrx Labs, LLC (collectively "Takeda") have brought suit under the Hatch-Waxman Amendments, 35 U.S.C. § 271(a),(b),(c), and/or (e)(2)(A), to enjoin Mylan Inc. and Mylan Pharmaceuticals, Inc. (collectively "Mylan") from obtaining FDA approval of their Abbreviated New Drug Application for a generic extended release tablet comprising a combination of pioglitazone hydrochloride and metformin hydrochloride. This tablet is intended to treat Type 2 diabetes. The plaintiffs allege that Mylan has infringed on ten of their patents.[1]

Pursuant to Markman v. Westview Instruments, Inc., 517 U.S. 370 (1996), Mylan has proposed constructions of claims in six of the ten patents.[2] Mylan does not contend that any term in the claims requires clarification. It argues instead that other portions in the patents' specifications require a limitation to be placed on claim terms. Takeda responds that no construction of the claims is necessary, but in any event that the

[1] United States Patents No. 5,965,584, 6,166,043, 6,172,090, 6,099,859, 6,495,162, 6,790,450, 6,866,866, 7,785,627, 7,919,166, 7,959,946, respectively, the '584, '043, '090, '859, '162, '450, '866, '627, '166, and '946 Patents.

[2] The disputed terms appear in the '627, '946, '859, '459, '866, and the '162 Patents.

specifications do not reflect an intent to limit the scope of the claims in the way proposed by Mylan.

Mylan's arguments rest on language found in several portions of the specifications: the abstracts for two of the patents, and in other sections of the specifications for all six patents. The only portion of Mylan's motion that has any conceivable merit is the portion that relies on the abstracts for two of the patents. That argument is considered at the end of this Opinion, following a description of the relevant legal principles and the specifications for the six patents, and the analysis and rejection of Mylan's argument addressed to all six patents. For the following reasons, Mylan's proposed constructions are rejected.

The patents at issue pertain to the product ACTOPLUS MET® XR. ACTOPLUS MET® XR is a once-daily, controlled release oral diabetes medicine used for treatment of Type 2 diabetes. It combines metformin hydrochloride and pioglitazone hydrochloride into a single product. The controlled release of a drug may help to regulate the exposure of a patient to the drug over time, assist a drug to reach a targeted site in the patient's body, and improve patient compliance with a drug regimen by reducing the required number of administrations.

Some controlled release drug delivery systems make use of an expanding polymer. An expanding polymer swells in the

presence of water or biological fluids. When used in a controlled release pharmaceutical tablet, an expanding polymer pushes the active ingredient, contained in the core of the tablet, out through a passageway in the drug capsule's membrane and into the patient's body. Mylan contends here that Takeda's patent claims require the non-employment of an expanding polymer.

Although Takeda contends that Mylan's arguments do not require any claim construction, this Opinion will address Mylan's contentions nonetheless. It is true that district courts are not required to construe every term appearing in a patent claim. 02 Micro Intern Ltd. V. Beyond Innovation Tech. Co. Ltd., 521 F.3d 1351, 1362 (Fed. Cir. 2008). Many words have an ordinary meaning that is evident to a lay person who is not skilled in the art at issue. Claim construction "is not an obligatory exercise in redundancy," and thus, if the parties have no actual dispute over the ordinary meaning of such a term, the court is not obligated to construe it. U.S. Surgical Corp. v. Ethicon Inc., 103 F.3d 1554, 1568 (Fed. Cir. 1997).

But, where the parties dispute "the scope of a claim term," the court has a duty to resolve the dispute. 02 Micro, 521 F.3d at 1362. Since the parties dispute whether the inventor has evidenced the intent in the specifications of these patents to

use the contested claim terms in a specialized manner, it is appropriate to address Mylan's proposed constructions.

"It is a bedrock principle of patent law that the claims of a patent define the invention to which the patentee is entitled the right to exclude." Phillips v. AWH Corp., 415 F.3d 1303, 1312 (Fed. Cir. 2005) (en banc). In construing a patent claim, which is a matter of law, terms are given their ordinary meaning, which is the meaning the terms would have to one of ordinary skill in the art in question. Id. at 1312-13. The heavy presumption of ordinary and customary meaning is overcome, however, if the patent evidences a sufficiently clear intent to define the term differently. CCS Fitness v. Brunswick Corp., 288 F.3d 1359, 1366 (Fed. Cir. 2002), see also Abraxis Bioscience, Inc. v. Mayne Pharma (USA) Inc., 467 F.3d 1370, 1376 (Fed. Cir. 2006); SciMed Life Systems, Inc. v. Advanced Cardiovascular Sys. Inc., 242 F.3d 1337, 1344 (Fed. Cir. 2001).

The primary source of meaning of a claim term is the intrinsic evidence, which includes the patent itself and its prosecution history. Vitronics Corp. v. Conceptronic, Inc., 90 F.3d 1576, 1582 (Fed. Cir. 1996). Ordinarily, a patent's specification is the most probative evidence of the patent's meaning, and is dispositive of the meaning of a disputed term in a claim. Phillips, 415 F.3d at 1315. Courts must tread carefully, however, for while they may use the specification to

construe disputed terms they must avoid the "danger of reading limitations from the specification into the claim" itself. Id. at 1323.

The specification usually contains an abstract, a description of the field of the invention, background on the invention, a summary of the invention, a detailed description of the invention, drawings, and lastly, the claims. The claims are the part of the patent that sets the metes and bounds on the patent holder's right to exclude. A claim can be further subdivided into a preamble, transition term, and the limitations.

Limiting language found in parts of the specification other than the claims, such as the stated objectives of the invention or any descriptions of preferred embodiments, should usually not be imported into the claims. See Brookhill-Wilk 1, LLC v. Intuitive Surgical, Inc., 326 F.3d 1215, 1223 (Fed. Cir. 2003); Electro Med. Sys., S.A. v. Cooper Life Scis., Inc., 34 F.3d 1048, 1054 (Fed. Cir. 1994). There are circumstances, however, in which the specification demonstrates with sufficient clarity that the invention is actually narrower than the ordinary meaning of the claim language would suggest. SciMed Life Sys., 242 F.3d at 1345. One situation in which the "specification may limit the scope of the claims," is where the inventor has acted as "his own lexicographer" and has used the specification

expressly to define terms that appear in the claims. Teleflex Inc. v. Ficosa N. Am. Corp., 299 F.3d 1313, 1325 (Fed. Cir. 2002). When this occurs, those definitions are controlling even if they vary from the ordinary and customary meaning of the claim terms. Vitronics Corp., 90 F.3d at 1582.

Additionally, "[t]he patentee may demonstrate an intent to deviate from the ordinary and accustomed meaning of a claim term by including in the specification expressions of manifest exclusion or restriction, representing a clear disavowal of claim scope." Teleflex Inc., 299 F.3d at 1325. In determining the significance of limiting language in the specification the court should examine "whether the specification refers to a limitation only as part of less than all possible embodiments or whether the specification read as a whole suggests that the very character of the invention requires the limitation be a part of every embodiment." Alloc Inv. v. Int'l Trade Comm'n, 342 F.3d 1361, 1370 (Fed. Cir. 2003). Thus, it is important "not to confuse exemplars or preferred embodiments in the specification that serve to teach and enable the invention with limitations that define the outer boundaries of claim scope." Intervet Inc. v. Merial Ltd., 617 F.3d 1282, 1287 (Fed. Cir. 2010).

Mylan does not contend through this motion that any term in the claims of the six patents does not have its common and ordinary meaning. Instead, it argues that material in other

parts of the specifications in the six patents reflects an intent to add a limitation to each claim. First, Mylan relies on two passages that appear in nearly identical language in each of the six patents' specifications. For two of the patents, Mylan also relies on the abstracts of those two patents. Therefore, this Opinion will address the issues common to all six patents before proceeding to a discussion of the impact of the abstracts on the construction of the claims in two patents: the '859 and '162 Patents.

A. The Specifications of the Six Patents

Mylan's argument with respect to each of the six patents rests on nearly identical language in the specifications and claims of these patents. In each instance, Mylan contends that language in the specification implies a limitation on the claims, specifically, a limitation on the use of an expanding polymer. A description of the '459 Patent will illustrate Mylan's argument.

The phrase in the '459 Patent claims on which Mylan seeks to impose a limitation reads: "[O]ral controlled release dosage form comprising an effective dose of metformin or pharmaceutically acceptable salt thereof."[3] Mylan argues that

[3] The claim language at issue in the other patents is the following: the '627 Patent: "oral pharmaceutical tablet

the phrase "that does not employ an expanding polymer"[4] should be added to follow this claim language.[5]

The language from the specification for the '459 Patent on which Mylan relies in making its argument is found in two sections: one section is entitled "Background of the Invention" ("Background") and the other is entitled "Objects and Summary of the Invention" ("Objects").[6] These portions of the specification follow the abstract and eight drawings and precede an eight-

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consisting of (a) a core" (All asserted claims); the '946 Patent: "a pharmaceutical dosage form having a first and second active drug, said dosage form comprising: (a) a controlled release core" (Claims 1-11); "a pharmaceutical dosage form comprising: (A) a controlled release osmotic tablet" (Claims 12-18); the '866 Patent: "a controlled release oral dosage form for the reduction of serum glucose levels in human patients with [noninsulin-dependent diabetes mellitus]" (All asserted claims); the '859 Patent: "a controlled release pharmaceutical tablet" (Claims 1-3, 5-8, 10, 13-22, and 24-26); "a controlled release antihyperglycemic tablet" (Claims 27-28); the '162 Patent: "a controlled release pharmaceutical tablet" (Claims 1, 3-9, 11, and 14-24); "a controlled release antihyperglycemic tablet" (Claims 25, 27-32, 34, and 37-45).

[4] Mylan seeks to add this same phrase to the '859, '162 and '866 Patents. With respect to the '627 and '946 Patents, Mylan seeks to add the phrase "that is not regulated by an expanding polymer" to the claim language.

[5] Mylan's proposed construction of the claims in the '459 Patent, in addition to adding the proposed language quoted above, also deletes from the claims the words "comprising an effective dose." Mylan has offered no explanation for this proposed deletion. It is a principal of claim construction that courts should not read claim terms to be superfluous or meaningless. Bicon, Inc. v. Straumann Co., 441 F.3d 945, 950 (Fed. Cir. 2006).

[6] These same statements appear in either the Background or Objects sections for all six patents.

paragraph section entitled "Brief Description of the Drawing" ("Drawing"), a twenty-six-paragraph section entitled "Detailed Description of the Invention" ("Detailed Description"), a section entitled "Description of Certain Preferred Embodiments" ("Embodiments") that contains three examples, a section on "Clinical Studies," and lastly, the twenty-one claims of the '459 Patent.

The "Background" consists of approximately 11 paragraphs. It includes a description of the prior art, specifically the techniques that have been used to provide the controlled release of a drug, and their refinements over time. It observes that while "vast amounts of research has [sic] been performed on controlled or sustained release compositions [generally] . . . very little research has been performed in the area of controlled or sustained release compositions that employ antihyperglycemic drugs." This observation is followed by a brief description of the antihyperglycemic drug metformin and the "limited" research that has been done on the controlled release of antihyperglycemic drugs. In this section, Mylan relies on the following language in support of its proposed claim construction: "The limited work on controlled or sustained release formulations that employ antihyperglycemic drugs such as metformin hydrochloride includes the combination of the

antihyperglycemic drug and an expanding or gelling agent to control the release of the drug from the dosage form."[7]

The "Background" is followed by the "Objects" section, which begins by listing eight separate objects of the invention. These objects include such goals as providing controlled release of an antihyperglycemic drug to provide "effective control of blood glucose levels"; providing "once-a-day" treatment; and insuring that "the bioavailability of the drug is not decreased by the presence of food." In making its claim construction argument, Mylan relies on the description of one of those eight objectives. That description reads as follows: "It is a further object of the present invention to provide a controlled or sustained release formulation of an antihyperglycemic drug that does not employ an expanding polymer."[8] The Objects section

[7] Identical language appears in the '866 Patent at 2:17-21 and nearly identical language appears in the '859 and '162 Patents ('859 Patent, 1:55-60; '162 Patent, 1:59-64). In the '946 and '627 Patents the following similar language appears in the "Background of the Invention": "Certain controlled or sustained release formulations that employ antihyperglycemic drugs such as metformin hydrochloride have been limited to the use of an expanding or gelling agent to control the release of the drug from the dosage form." The patents proceed to describe this as "limited research." '946 Patent, 1:62-66; '627 Patent, 1:59-63.

[8] Identical language appears in the '459, '866, and '162 Patents ('459 Patent, 3:5-7; '866 Patent, 3:3-5; '162, 2:16-19). The following similar language appears in the '627 and '946 Patents: "It is a further object of the present invention to provide a dosage form . . . wherein said controlled or sustained release mechanism is not regulated by an expanding polymer. . . ." '627 Patent, 2:48-53; '946 Patent, 2:51-56.

continues to describe at great length embodiments and preferred embodiments of the present invention. The section ends by laying out definitions for a number of key terms including "dosage form,"[9] "sustained release" and "controlled release."[10]

The next section in the specification, which is the "Drawing" section, explains what is depicted in each of the eight drawings that appear earlier in the patent. This is followed by the "Detailed Description" section, which compares the methods and dosage forms of the present invention to the administration of GLUCOPHAGE®, an exemplar of the prior art. The "Detailed Description" section also provides greater detail on the components of certain embodiments of the invention.

The "Embodiments" section contains three examples of the composition and construction of controlled release tablets. In each example, the granulation, tableting, seal coating and laser

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[9] Dosage form is defined as "at least one unit dosage form of the present invention (e.g. the daily dose of the antihyperglycemic agent can be contained in 2 unit dosage forms of the present invention for single once-a-day administration)."

[10] The patent provides that "sustained release" and "controlled release" are "used interchangeably in this application and are defined for purposes of the present invention as the release of the drug from the dosage form at such a rate that when a one-a-day dose of the drug is administered in the sustained release or controlled-release form, blood (e.g., plasma) concentrations (levels) of the drug are maintained within the therapeutic range but below toxic levels over a period of time from about 12 to about 24 hours."

drilling of the tablets are described. The preferred embodiments do not explicitly discuss the employment or non-employment of an expanding polymer.[11] In the final section that precedes the claims, four clinical studies are described.

B. The Import of the Background and Objects Sections

After considering the claims and construing them in light of the specification, Mylan's proposed claim construction fails. First, and most significantly, nothing in the claim language to which Mylan points refers to the absence or presence of an expanding polymer. No single word contained in this portion of the claims, nor any of the words used in conjunction with each other, possesses an ordinary and customary meaning akin to either "does not employ an expanding polymer" or "is not regulated by an expanding polymer." Mylan therefore bears a heavy burden to show that the remaining portions of the patent's specification evince an intent to add the limitation proffered by Mylan.

[11] The '627 and '946 Patents contemplate that at least one embodiment will not employ an expanding polymer: "In one embodiment of the present invention, which does not employ a gelling or swelling polymer, the core of the present invention is preferably formed by granulating an antihyperglycemic drug with a binding agent and compressing the granules with the addition of a lubricant and absorption enhancer into a tablet." The '627 Patent, 4:60-65; the '946 Patent, 5:11-16.

Second, there is no evidence that the inventor acted as his own "lexicographer" in the sections of the specification preceding the claims. There is nothing in the specifications that could be reasonably read as the assignment of a specialized definition for the claim terms that would encompass Mylan's proposed limitation.[12]

Finally, Mylan has not shown that any portion of the specification demonstrates with sufficient clarity that the patent actually includes the limitation that the ordinary meaning of the claims does not suggest. As noted, Mylan relies on two passages, one from the Background and the other from the Objects section, to argue that there has been a "clear intent" to read a limitation onto the claims. Neither passage can bear that weight.

The passage in the Background to which Mylan points is nothing more than a description of the limited research that had been done previously on the controlled release of metformin hydrochloride. The passage in the Objects is simply one of eight listed objects of the invention. Neither a stated object of an invention, nor a stated advantage of an invention over

[12] The patent does expressly define some of the individual words that are a part of the claims that Mylan seeks to amend, such as "metformin," "controlled release" and "dosage form." The definitions that the patent provides for "metformin," "controlled release" and "dosage form" make no reference to the employment or non-employment of an expanding polymer. The '459 Patent, 6:65-67, 7:1-5.

prior art, will create a limitation unless there has been a "clear disclaimer." Northrop Grumman Corp v. Intel Corp., 325 F.3d 1346, 1355 (Fed. Cir. 2003). "The fact that a patent asserts that an invention achieves several objectives does not require that each of the claims be construed as limited to structures that are capable of achieving all of the objectives." Phillips, 415 F.3d at 1327. Mylan cannot, therefore, use one of eight listed objects of the patent to create a limitation on claim terms. As the Federal Circuit has observed, "adding limitations to claims not required by the claim terms themselves, or unambiguously required by the specification or prosecution history, is impermissible." Dayco Products, Inc. v. Total Containment, Inc., 258 F.3d 1317, 1327 (Fed. Cir. 2001).

In conclusion, Mylan has utterly failed to show an intent to add the phrase "that does not employ an expanding polymer" to the claim language "oral controlled release dosage form comprising an effective dose of metformin or a pharmaceutically acceptable salt thereof." No fair reading of the two passages to which Mylan points, contained in the Background and Objects sections of the '459 Patent specification, supports its construction. The specification is detailed and lengthy. Having examined the specification in its entirety, Mylan's proposed construction of the claims, premised on these two passages, is easily rejected.

Mylan makes principally two arguments to support its contention that these two passages in the specification require that the limitation be read onto the '459 Patent's claims. First, it points out that disparagement of prior art can result in constriction of claim scope. This is true where the disparagement rises to the level of a "clear" disavowal. SciMed Life Sys., 242 F.3d at 1344. But, mere criticism or general statements distinguishing prior art from the present invention are insufficient to effect a disclaimer. "The patentee may demonstrate intent to deviate from the ordinary and accustomed meaning of a claim term by including in the specification expressions of manifest exclusion or restriction, representing a clear disavowal of claim scope." Thorner v. Sony Computer Entertainment America LLC, 669 F.3d 1362, 1366 (Fed. Cir. 2012) (citation omitted); see Ventana Medical Systems, Inc. v. Biogenex Laboratories, Inc., 473 F.3d 1173, 1181 (Fed. Cir. 2006). The passage in the Background on which Mylan relies in making its argument does not constitute a clear disavowal; it isn't even a disparagement or criticism of prior art. The passage does no more than describe the prior art. It notes that the limited work that had been previously done on controlled release formulations that employed drugs such as metformin hydrocholoride included the use of "an expanding or gelling agent to control the release." Thus, the passage in the

Background cannot be read to disclaim the use of an expanding polymer.

Mylan next contends that the language in the specification identifying the non-employment of an expanding polymer as an object of the invention suggests that "the very character of the invention requires" the non-employment of an expanding polymer to "be a part of every embodiment." Alloc Inv., 342 F.3d at 1370. Mylan overstates the import of the single objective to which it refers. This single objective, which is only one of eight objectives, does not require that the invention as a whole be characterized by the non-employment of an expanding polymer.

Nor is Mylan's argument strengthened by its reliance on Alloc. In Alloc, the patents disclosed systems and methods of joining floor panels. One issue in the case was whether the claims should be construed to require "play" between the panels. Id. at 1367. In concluding that the "play" limitation was properly imposed, the Federal Circuit noted that the claims themselves recited features in which "play is necessarily present," that the specification taught "that the invention as a whole, not merely a preferred embodiment provides for play," and that all of the disclosed embodiments imply play. Id. at 1368-70. In contrast, the '459 Patent does not criticize the prior art's employment of an expanding polymer, its preferred embodiments do not expressly require the non-employment of an

expanding polymer, and reading the specification of the patent as a whole, there is nothing to suggest that the "very character of the invention requires the [non-employment of an expanding polymer] limitation be a part of every embodiment." Id. at 1370.

The foregoing analysis of the '459 Patent applies with equal force to the remaining five Patents. The two passages appearing in the '459 Patent on which Mylan relies for its proposed construction are essentially indistinguishable from the passages on which Mylan relies for its construction of the claims in the other five patents. As just described, those two passages do not demonstrate that the non-employment of an expanding polymer is an essential feature of the inventions. In sum, these passages are insufficient to support Mylan's proposed limitation on the patents' claims.

For two of these six patents, there are additional reasons why Mylan's arguments must be rejected. First, Mylan's proposed limitation is barred by the doctrine of claim differentiation. Second, the specifications of the '627 and '946 Patents explicitly reject Mylan's argument that the non-employment of an expanding polymer is an essential feature of the inventions.

C. Claim Differentiation and the '946 Patent

The doctrine of claim differentiation militates strongly against imposing a "non-employment of an expanding polymer" limitation on the claims of the '946 Patent. The doctrine of claim differentiation posits that "[d]ifferences among claims can . . . be a useful guide in understanding the meaning of particular claim terms." Phillips, 415 F.3d at 1314. "For example, the presence of a dependent claim that adds a particular limitation gives rise to a presumption that the limitation in question is not present in the independent claim." Id. at 1314-1315.

In the '946 Patent, claim 1 is an independent claim that contains one of the two terms on which Mylan seeks to impose a limitation. It reads: "A pharmaceutical dosage form having a first and second active drug, said dosage form comprising: (a) a controlled release core." Claim 8 is a dependent claim that reads as follows: "The dosage form of claim 1 wherein said core is substantially free from any gelling or expanding polymer." Under a straightforward application of the doctrine of claim differentiation, the term in claim 1 cannot require the absence of an expanding polymer. Otherwise, the limitation in claim 8 would be superfluous.

Similarly, claim 12 is an independent claim that contains the other term on which Mylan seeks to impose a limitation. It

reads: "A pharmaceutical dosage form comprising: (A) a controlled release osmotic tablet". Claim 15 is a dependent claim that reads as follows: "The dosage form of claim 12 wherein said osmotic tablet core is substantially free from any gelling or expanding polymer." Once again, applying the doctrine of claim differentiation, the claim "A pharmaceutical dosage form comprising (A) a controlled release osmotic tablet" does not require the absence of an expanding polymer. To state the obvious, if claim 12 did bar the use of an expanding polymer, then there would be no purpose served by adding claim 15 to the patent.

Mylan responds to this evidence by noting that the canon of claim differentiation "is not a rigid rule," Karlin Tech., Inc. v. Surgical Dynamics, Inc., 177 F.3d 968, 972 (Fed. Cir. 1999), and can be overcome "by a contrary construction dictated by the written description or prosecution history." Seachange Int'l, Inc. v. C-Cor Inc., 413 F.3d 1361, 1369 (Fed. Cir. 2005). These well established legal principles do little to assist Mylan. While the presumption of claim differentiation can be overcome, no passage in the specification for the '946 Patent dictates the non-employment of an expanding polymer.

D. Explicit Employment of an Expanding Polymer in the '627 and '946 Patents

Mylan's proposed construction of the '627 and '946 Patents fails for yet one more reason. The specifications in the '627 and '946 Patents explain that an expanding polymer may be used in some embodiments of the inventions.[13] For example, the "Summary of the Invention" for the '627 Patent states:

> The foregoing objectives are met by a dosage form comprising a first and second active drug . . . with or without a gelling or expanding polymer.

'627 Patent, 3:34-38 (emphasis supplied). Similarly, in the "Detailed Description of the Invention," the '946 Patent provides:

> The antihyperglycemic drug is delivered in a controlled release manner from a tablet core, preferably an osmotic tablet core with or without a gelling or swelling polymer.

'946 Patent, 4:24-27 (emphasis supplied). Because these two patents expressly contemplate the presence of expanding polymers in some embodiments of the inventions, their claims cannot be read to bar the employment of an expanding polymer.

[13] In an untimely argument in briefing on an unrelated issue, Mylan strains to escape the clear import of these explanations. Mylan argues that the instruction that an expanding polymer may be present is of little significance to its claim construction since the instruction does not indicate that the polymer, even if present, would actually be employed.

E. The Abstracts of the '859 and '162 Patents

Mylan has a second claim construction argument that applies to just two of the six patents. It relies on the abstracts to the '859 and '162 Patents to argue that an express disclaimer of the employment of expanding polymers must be added to the following clauses in the claims: for the '859 Patent, "A controlled release pharmaceutical tablet" (Claims 1-3, 5-8, 10, 13-22, 24-26); "A controlled release antihyperglycemic tablet" (Claims 27-28); and for the '162 Patent, "A controlled release pharmaceutical tablet" (Claims 1, 3-9, 11, 14-24); "A controlled release antihyperglycemic tablet" (Claims 25, 27-32, 34, 37-45).

Mylan argues that the abstract portion of the specifications has expressly disclaimed the employment of expanding polymers. Both abstracts describe the claimed invention as "[a] controlled release antihyperglycemic tablet that does not contain an expanding polymer." (Emphasis supplied.)

The abstract of a patent is usually the first section in a specification. Its purpose "is to enable the United States Patent and Trademark Office and the public generally to determine quickly from a cursory inspection the nature and gist of the technical disclosure." 37 C.F.R. § 1.72(b). An abstract is a "potentially helpful source of intrinsic evidence" for purposes of claim construction. Hill-Rom Co., Inc. v. Konetic

Concepts, Inc., 209 F.3d 1337, 1341 n.* (Fed. Cir. 2000). Consequently, a court may consider the abstract, in addition to the other parts of the specification, to determine whether limiting language describes a preferred embodiment of the invention or, instead, describes the invention as a whole.

In this case, the abstracts, whether considered alone or in conjunction with the other statements from the specifications upon which Mylan relies, do not describe the invention as a whole. Instead, when the specifications of these two patents are considered in their entirety, their abstracts are more properly understood as describing a preferred embodiment of the invention, that is, one in which an expanding polymer is absent. Because descriptions of preferred embodiments do not ordinarily limit the scope of patent claims, Mylan's request to read a "non-employment of an expanding polymer" limitation into the disputed terms is denied. Liebel-Flarsheim Co. v. Medrad, Inc., 358 F.3d 898, 913 (Fed. Cir. 2004).

Mylan relies particularly on C.R. Bard, Inc. v. U.S. Surgical Corp., 388 F.3d 858, 864 (Fed. Cir. 2004), and SciMed Life Sys., 242 F.3d 1337, to support its argument that the specifications of the '859 and '162 Patents expressly disclaim the presence of an expanding polymer. In C.R. Bard, the patent disclosed a device to repair hernias. The court construed the claim term "plug" to mean a "pleated" plug. Id. at 863. In

doing so it emphasized the general descriptions of the device in two places in the specification –- the "Summary of the Invention" and the "Abstract." Id. at 864. The Summary of the Invention stated that the claimed "implant includes a pleated surface;" the Abstract described a "plug having a pleated surface." Id. (emphasis omitted). The court added that "statements [in the specification] describing preferred embodiments of the surface of the plug universally describe a 'pleated conical plug.'" Id. at 866.

In SciMed Life Sys., the patents claimed balloon dilation catheters used in coronary angioplasty procedures. SciMed Life Sys., 242 F.3d at 1339. The catheters contained two passageways, known as lumens. The only known arrangements for the lumens were 1) the dual lumen configuration and 2) the coaxial lumen configuration. Although the claim language did not expressly disclose the configuration, the Federal Circuit interpreted "the specification to disclaim the dual lumen configuration and to limit the scope of the asserted claims to catheters with coaxial lumen structures." Id. at 1340. In addition to relying on language in the abstract, the court emphasized that the specification distinguished the present invention over the prior art by pointing out the disadvantages of the dual lumen configuration in the prior art. Id. at 1342-43. Even more importantly, the "Summary of the Invention"

characterized the "present invention" in several places as having a coaxial configuration, id. at 1343, and the section entitled "Catheter Intermediate Sleeve Section" stated that the coaxial configuration was the "basic" structure "for all embodiments of the present invention contemplated and disclosed herein." Id. at 1343.

The decision in SciMed Life Sys. requires little discussion. The court drew on numerous general descriptions of the device in the specification to import a limitation into the claims. There is no equivalent in the '859 or '162 Patents. The Patents do not contain repeated general descriptions of the invention that exclude the use of an expanding polymer. At best there is one general description in the abstract, which as already discussed, is insufficient to find a clear intent to limit the scope of the claims. The decision in C.R. Bard presents a somewhat harder case. But, again, the Federal Circuit relied on multiple general descriptions of the device to find a limitation, and, fairly read, the '859 and '162 Patents each have only one such general description, the one found in the abstracts for the two patents.

The analysis contained in Liebel-Flarsheim Co. v. Medrad, Inc., 358 F.3d 898 (Fed. Cir. 2004), is particularly instructive on this point. In Liebel-Flarsheim, the patents claimed methods and devices for powered fluid injectors intended for use during

medical procedures. Id. at 900. The Federal Circuit refused to construe the claims to require the use of pressure jackets surrounding the injector or syringe, despite restrictive language in the abstracts. Id. at 903. The abstracts stated that an "animal fluid injector, replaceable syringe and method of replacement of the syringe in the injector are provided in which the syringe is loadable and unloadable into and from the injector through the open front end of a pressure jacket of the injector." Id. at 908 (emphasis supplied). The Federal Circuit addressed this language by stating:

> Although, that language can reasonably be understood as constituting a general description of the invention, the quoted passage does not suggest that a pressure jacket is an essential component of the invention, nor is there any language in that passage, or elsewhere in the specification, that disclaims the use of the invention in the absence of a pressure jacket.

Id. Notably, the Federal Circuit refused the proffered construction of the claims as one requiring pressure jackets despite the fact that every embodiment included a pressure jacket and one of the stated objects of the invention described a pressure jacket. Id. These and other references in the specification to a pressure jacket prompted the Federal Circuit to caution that "absent a clear disavowal of particular subject matter, the fact that the inventor may have anticipated that the invention would be used in a particular way does not mean that

the scope of the invention is limited to that context." Id. at 909 (citation omitted).

Similarly, the statements contained in the abstracts of the '859 and '162 Patents should be understood as descriptions of a preferred embodiment of the invention. Accordingly, the claim terms for these two patents are to be given their ordinary meaning; they do not require the non-employment of an expanding polymer.

CONCLUSION

Mylan's July 20, 2012 motion to construe the claims in the '627, '946, '859, '162, '866 and '459 Patents to require the non-employment of an expanding polymer is denied.

SO ORDERED:

Dated: New York, New York
October 11, 2011

DENISE COTE
United States District Judge